

We Claim:

1. A method for detecting kallikrein 5 associated with breast or ovarian cancer in a patient comprising:
  - (a) taking a sample derived from a patient;
  - (b) detecting in the sample kallikrein 5; and
  - (c) comparing the detected amount with an amount detected for a standard.
2. A method for diagnosing and monitoring breast or ovarian carcinoma in a subject comprising detecting kallikrein 5 in a sample from the subject.
3. A method as claimed in claim 1 or 2 wherein the kallikrein 5 is detected using antibodies specifically reactive with kallikrein 5 or a part thereof.
4. A method of detecting breast or ovarian cancer in a patient, the method comprising comparing:
  - (a) levels of kallikrein 5 in a sample from the patient; and
  - (b) normal levels of expression of a kallikrein 5 in a control sample, wherein a significant difference in levels of kallikrein 5, relative to the corresponding normal levels, is indicative of breast or ovarian cancer.
5. A method for screening a subject for breast or ovarian cancer comprising (a) obtaining a biological sample from a subject; (b) detecting the amount of kallikrein 5 in said sample; and (c) comparing said amount of kallikrein 5 detected to a predetermined standard, where detection of a level of kallikrein 5 greater than that of a standard is indicative of breast or ovarian cancer.
6. A method of claim 5 wherein the level of kallikrein 5 is 2X, 5X, 10X, 15X, or 20X the levels of the standard.
7. A method of assessing whether a patient is afflicted with or has a pre-disposition for breast or ovarian cancer, the method comprising comparing:
  - (a) levels of kallikrein 5 in a sample from the patient; and
  - (b) normal levels of kallikrein 5 in samples of the same type obtained from control patients not afflicted with breast or ovarian cancer, wherein significantly higher levels of kallikrein 5, relative to the corresponding normal levels of the kallikrein 5, is an indication that the patient is afflicted with breast or ovarian cancer.
8. A method of claim 7 wherein the levels of kallikrein 5 are 2X, 5X, 10X, 15X, or 20X the normal levels.
9. A method for monitoring the progression of breast or ovarian cancer in a patient, the method comprising:
  - (a) detecting in a sample from the patient at a first time point, kallikrein 5;
  - (b) repeating step (a) at a subsequent point in time; and
  - (c) comparing levels detected in steps (a) and (b), and thereby monitoring the progression of breast or ovarian cancer.
10. A method for screening a subject for breast or ovarian cancer comprising
  - (a) incubating a biological sample from the subject with a first antibody specific for kallikrein 5 which is directly or indirectly labeled with a detectable substance, and a second antibody

specific for kallikrein 5 which is immobilized;

- (b) detecting the detectable substance thereby quantitating kallikrein 5 in the biological sample; and
  - (c) comparing the quantitated kallikrein 5 with levels for a predetermined standard.
- 5 11. A method of any preceding claim wherein the biological sample is serum.
12. A method of any preceding claim which further comprises detecting one or more of human stratum corneum chymotryptic enzyme (HSCCE), haptoglobin alpha, osteopontin, kallikrein 2, kallikrein 3, kallikrein 4, kallikrein 6, kallikrein 7, kallikrein 8, kallikrein 9, kallikrein 10, kallikrein 11, kallikrein 13, kallikrein 14, kallikrein 15, CA125, CA15-3, CA19-9, OVX1, lysophosphatidic acid (LPA) or carcinoembryonic antigen (CEA).
- 10 13. A method for assessing the potential efficacy of a test agent for inhibiting breast or ovarian cancer in a patient, the method comprising comparing: (a) levels of kallikrein 5 in a first sample obtained from a patient and exposed to the test agent; and (b) levels of kallikrein 5 in a second sample obtained from the patient, wherein the sample is not exposed to the test agent, wherein a significant difference in the levels of expression of kallikrein 5 in the first sample, relative to the second sample, is an indication that the test agent is potentially efficacious for inhibiting breast or ovarian cancer in the patient.
- 15 14. A method of claim 13 wherein the first and second sample comprises portions of a single sample obtained from the patient.
- 20 15. A method of claim 13 wherein the first and second sample comprises portions of pooled samples obtained from the patient.
16. A method of assessing the efficacy of a therapy for inhibiting breast or ovarian cancer in a patient, the method comprising comparing: (a) levels of kallikrein 5 in a first sample obtained from the patient, and (b) levels of kallikrein 5 in a second sample obtained from the patient following therapy, wherein a significant difference in the levels of expression of kallikrein 5 in the second sample, relative to the first sample, is an indication that the therapy is efficacious for inhibiting breast or ovarian cancer in the patient.
- 25 17. A method of selecting an agent for inhibiting breast or ovarian cancer in a patient the method comprising (a) obtaining a sample of cells affected by breast or ovarian cancer from the patient; (b) separately exposing aliquots of the sample in the presence of a plurality of test agents; (c) comparing levels of kallikrein 5 in each of the aliquots; and (d) selecting one of the test agents which alters the levels of kallikrein 5 in the aliquot containing that test agent, relative to other test agents.
- 30 18. A method of inhibiting breast or ovarian cancer in a patient, the method comprising:
- 35 (a) obtaining a sample comprising cells affected by breast or ovarian cancer from the patient;
- (b) separately maintaining aliquots of the sample in the presence of a plurality of test agents;
- (c) comparing levels of kallikrein 5 in each of the aliquots; and
- (d) administering to the patient at least one of the test agents which alters the levels of kallikrein 5 in the aliquot containing that test agent, relative to other test agents.

19. A method of claim 17 or 18 wherein the test agent reduced levels of kallikrein 5 in the aliquots.
20. A method of assessing the potential of a test compound to contribute to breast or ovarian cancer, the method comprising: (a) maintaining separate aliquots of cells affected by the breast or ovarian cancer in the presence and absence of the test compound; and (b) comparing expression of kallikrein 5 in each of the aliquots, and wherein a significant difference in levels of kallikrein 5 in the aliquot maintained in the presence of the test compound, relative to the aliquot maintained in the absence of the test compound, is an indication that the test compound possesses potential to contribute to breast or ovarian cancer.
21. A method for imaging a breast or ovarian cancer tissue comprising administering to a tissue of a subject with breast or ovarian cancer imaging agents that carry imaging labels and are capable of targeting or binding to kallikrein 5 and optionally other breast or ovarian cancer markers in the tissue.
22. An *in vivo* method for imaging breast or ovarian cancer comprising:
- (a) injecting a patient with an imaging agent that binds to kallikrein 5, the imaging agent carrying a label for imaging the cancer;
  - (b) allowing the imaging agent to incubate *in vivo* and bind to kallikrein 5 associated with the cancer; and
  - (c) detecting the presence of the label localized to the cancer.
23. A method as claimed in claim 22 wherein the imaging agent is an antibody which recognizes kallikrein 5.
24. A method as claimed in claim 22 wherein the label is a radiolabel, fluorescent label, nuclear magnetic resonance active label, positron emitting isotope detectable by a positron emission tomography ("PET") scanner, chemiluminescer, or enzymatic marker.
25. A kit for carrying out a method as claimed in any preceding claim.
26. A kit for assessing whether a patient is afflicted with breast or ovarian cancer, the kit comprising reagents that specifically bind with kallikrein 5.
27. A kit for assessing the suitability of each of a plurality of agents for inhibiting breast or ovarian cancer in a patient, the kit comprising: (a) the plurality of agents; and (b) reagents for detecting kallikrein 5.
28. A kit as claimed in claim 26 or 27 wherein the reagents are antibodies that specifically bind with protein or protein fragments corresponding to kallikrein 5.